REMARKS

Claim 1 is pending in the instant application. Claim 1 has been rejected. Claim 1 has been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

I. Rejection of Claims Under 35 U.S.C. §103

Claim 1 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Stewart et al. ((1992) *Biol. Reprod.* 46:648-52) in view of Stewart et al. ((1982) *J. Reprod. Fertil.* 32:603-9).

The Examiner suggests that Stewart et al. (1992) teaches a method for measuring levels of relaxin in plasma of a pregnant mare before and after the administration of a drug or treatment wherein a homologous equine relaxin RIA has been developed and used to measure plasma relaxin activity in thoroughbred mares during gestation until the time of foaling. Burros and Thoroughbred mares stimulated to deliver with oxytocin (treatment) showed an elevation in relaxin levels wherein the sensitivity to oxytocin appears to develop late in gestation as mares induced to abort in midpregnancy did not show a rise in relaxin. Animals that exhibited adverse pregnancy outcomes had depressed relaxin concentrations at some point during gestation prior to the loss. It is suggested that Stewart et al. (1992) does not teach the evaluation of a treatment wherein the failure of the plasma relaxin levels to increase following a treatment or drug is indicative of a non-effective treatment in preventing problematic pregnancy or delivery in the mare.

The Examiner suggests that Stewart et al. (1982) teaches the administration of oxytocin in pregnant mares results in an

increase of plasma relaxin levels at foaling and after foaling, but when oxytocin was administered to mares after placental delivery, the mares failed to elicit an increase in relaxin levels.

The Examiner concludes that it would have been obvious to one of ordinary skill in the art to modify the teaching of Stewart et al. (1992) to include evaluating oxytocin as a treatment for conditions that alter placental function because increase and decrease in relaxin levels are directly correlated with placental function as disclosed in Stewart et al. (1982). Applicants respectfully disagree.

A central issue to this rejection is the state of the animals being evaluated and the expected outcome upon administration of a drug or treatment. Stewart et al. (1992) and Stewart et al. (1982) teach measurements of relaxin in healthy animals induced to foal with oxytocin. Animals in these studies which had abnormal pregnancies did not receive any treatment in support of bringing the pregnancy to term. See page 65, column 2 of Stewart et al. (1992). In contrast, the method of the present invention is used to evaluate treatment efficacy in pregnant mares affected by a disease or condition that alters placental function thereby adversely affecting the outcome of the pregnancy. In measuring the levels of relaxin, one can monitor whether a particular drug or treatment is having a beneficial effect on pregnancy such that the outcome is improved, *e.g.*, a full-term pregnancy.

At the outset, Applicants wish to point out that while oxytocin is indeed a drug, it is a peptide hormone, secreted by the pituitary gland, that stimulates contractions of the uterus

or oviduct and ejection of milk in mammals. It is recognized in the art of equine reproduction that oxytocin is used to treat mares for flushing uterine fluid, for induction of parturition, and for retained placenta. It is further used for promoting uterine involution, lactation and maternal behavior. Oxytocin is generally used to induce delivery of a foal and to help restore the uterus to the non-pregnant state following parturition. Inappropriate administration of oxytocin during gestation will lead to premature termination of a pregnancy in the mare. Therefore, oxytocin is not established in the art as a drug used for the treatment of a disease or condition that alters placental function so that *a problematic pregnancy or delivery in a mare is prevented*. Accordingly, upon reading the disclosures of Stewart et al. (1992) and Stewart et al. (1982) which teach the use of oxytocin and the corresponding levels of relaxin, it would not be obvious to one of skill in the art that a positive correlation exists between improved pregnancy outcome upon treatment of a disease or condition and an increase in circulating relaxin levels.

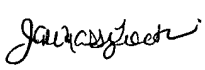
In an effort to further clarify the present invention, Applicants have amended claim 1 to recite that the intended result of administering a drug or treatment in pregnant mares affected by a disease or condition that alters placental function is to improve pregnancy outcome. Claim 1 has also been amended to indicate that relaxin levels are measured in blood. Support for these amendments can be found at pages 7-9 which demonstrate that the levels of relaxin in the blood correlate with treatment efficacy in mares affected by diseases or conditions that affect placental function, wherein treatment of the disease or condition

is intended to improve pregnancy outcome not prematurely terminate pregnancy. In view of this amendment and the accompanying remarks, it is respectfully requested that this rejection be withdrawn.

II. Conclusion

The Applicants believe that the foregoing comprises a full and complete response to the Office Action of record. Accordingly, favorable reconsideration and subsequent allowance of the pending claim is earnestly solicited.

Respectfully submitted,



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Date: **October 27, 2004**

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